

Serial No. 10/529,449  
Amendment dated May 2, 2007  
Official Action dated February 2, 2007

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**REMARKS**

The Office Action dated February 2, 2007 has been carefully considered.

Accordingly, the changes presented herewith, taken with the following remarks, are believed sufficient to place the present application in condition for allowance. Reconsideration is respectfully requested.

By the present amendment, independent claims 1 and 11 have been amended to recite a ring-opening (co)polymer of glycolide or a mixture containing at least 70% by weight of glycolide and at most 30% by weight of another cyclic monomer, as disclosed in the present specification at page 8, line 17 to page 9, line 20, and in the Examples. Claims 1 and 11 have also been amended to recite that the ring-opening (co)polymer before the chain lengthening has a weight average molecular weight of at least 30,000 and is subjected to the chain-lengthening reaction to produce the high-molecular weight ring-opening (co)polymer, as disclosed in the present specification at page 11, lines 17 to 23. Further, claims 1 and 11 have been amended to recite that the difference ( $T_2 - T_1$ ) is at least 5°C, as disclosed in the present specification at page 18, lines 2 to 11.

Claim 11 has also been amended to recite that the ring-opening (co)polymer and the oxazoline compound are subjected to the chain-lengthening reaction under conditions wherein the reaction temperature is not lower than the melting temperature of the ring-opening (co)polymer, but not higher than 300°C, and the reaction time is 10 to 30 minutes, as disclosed in the present specification at page 14, lines 8 to 19. Claims 2, 3, 6, 12-15 and 19 have been canceled from the application, claim 5 has been amended to correspond with claim

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1, claim 7 has been amended to change its dependency from canceled claim 6 to claim 1, and claims 4, 8 and 20 are amended for clarity.

Claims 21-28 have been added. Support for claims 21 and 27 may be found in the present specification at page 17, lines 12 to 19. Support for claims 22 and 25 may be found in the present specification at page 18, lines 2 to 20. Support for claim 23 may be found in the present specification at page 14, lines 8 to 19. Support for claim 24 may be found in claim 7. Support for claim 26 may be found in the present specification at page 13, lines 9 to 21. Support for claim 28 may be found in the present specification in claim 10.

It is believed that these changes do not involve any introduction of new matter, thereby the entry of the amendments is believed to be in order and is respectfully requested.

In the Official Action, claims 1-4, 6-14, 16, 17 and 19-20 were rejected under 35 U.S.C. § 102 (b) as anticipated by Matsumoto (JP 2001-323056). However, set forth in detail below, Applicants submit that the high-molecular weight aliphatic polyesters and production processes thereof defined by the present claims 1, 4, 7-11, 16, 17 and 20 are not anticipated by Matsumoto et al. Accordingly, this rejection is respectfully traversed and reconsideration is respectfully requested.

As defined by claim 1, the present invention relates to a high-molecular weight aliphatic polyester, whose molecular weight has been highly increased by a chain-lengthening reaction of a ring-opening (co)polymer of glycolide or a mixture containing at least 70% by weight of glycolide and at most 30% by weight of another cyclic monomer with an oxazoline compound to the extent that a ratio of increase in molecular weight represented by a ratio

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( $Mw_2/Mw_1$ ) of a weight average molecular weight ( $Mw_2$ ) of the ring-opening (co)polymer after the chain lengthening to a weight average molecular weight ( $Mw_1$ ) of the ring-opening (co)polymer before the chain lengthening amounts to at least 1.35. The ring-opening (co)polymer has a weight average molecular weight of at least 30,000 before the chain lengthening and is subjected to the chain-lengthening reaction to produce the high-molecular weight ring-opening (co)polymer. A difference ( $T_2 - T_1$ ) between a 1%-weight loss-starting temperature  $T_2$  on heating of the ring-opening (co)polymer after the chain lengthening and a 1%-weight loss-starting temperature  $T_1$  on heating of the ring-opening (co)polymer before the chain lengthening is at least 5°C.

As defined by claim 11, in the process for producing a high-molecular weight aliphatic polyester according to the present invention, the ring-opening (co)polymer and the oxazoline compound are subjected to the chain-lengthening reaction under conditions wherein the reaction temperature is not lower than the melting temperature of the ring-opening (co)polymer, but not higher than 300°C, and the reaction time is 10 to 30 minutes.

Thus, the aliphatic esters in independent claims 1 and 11 are polyglycolic acid homopolymer or copolymer, and, more specifically, the high-molecular weight aliphatic polyester according to the present invention is a high-molecular weight polyglycolic acid, whose molecular weight has been highly increased by a chain-lengthening reaction of a ring-opening (co)polymer of glycolide or a mixture containing at least 70% by weight of glycolide and at most 30% by weight of another cyclic monomer with an oxazoline compound. According to the present invention, the chain-lengthening reaction is caused by reacting the polyglycolic acid obtained by the ring-opening (co)polymerization of glycolide with the

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oxazoline compound at a high temperature of not lower than the melting temperature of the polyglycolic acid, but not higher than 300°C and in a reaction time of 10 to 30 minutes. The present specification describes that

"The reaction with such an oxazoline compound is a chain-lengthening reaction, in which significant increase in the molecular weight of the ring-opening (co)polymer is observed, different from a mere chain-terminating reaction."  
(Page 15, lines 11 to 15)

According to the process of the present invention, high-molecular weight polyglycolic acid, whose molecular weight has been highly increased to the extent that a ratio of increase in molecular weight amounts to at least 1.35, is obtained. This ratio of increase in molecular weight is by no means a low level. The Examples of the present specification (summarized in Table 1 at page 24) show that high-molecular weight polyglycolic acid, whose weight average molecular weight (Mw) had been increased to 173,000 to 235,000, was obtained by the chain-lengthening reaction of polyglycolic acid having Mw of 110,000 with an oxazoline compound. It is extremely difficult or substantially impossible to synthesize such high-molecular weight polyglycolic acid by the conventional ring-opening polymerization process.

In addition, according to the process of the present invention, high-molecular weight polyglycolic acid excellent in heat resistance, whose difference ( $T_2 - T_1$ ) is at least 5°C, can be obtained by the described chain-lengthening reaction. The prior art does not teach, suggest or recognize the claimed high-molecular weight polyglycolic acid markedly improved in heat resistance that is obtained by the chain-lengthening reaction with the oxazoline compound as described above and presently claimed.

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Particularly, Matsumoto et al provide no teaching of polyesters or processes as claimed, or the improvements thereof. That is, Matsumoto et al disclose "an aliphatic polyester resin characterized in that a part or substantially the whole of carboxyl end groups of an aliphatic polyester is terminated by one or more compounds selected from oxazoline compounds and oxazine compounds." (claim 1). Matsumoto et al describe that "The present invention relates to an aliphatic polyester resin and moldings thereof, and more particularly to an aliphatic polyester resin, whose acid end groups are terminated to improve resistance to hydrolysis, and moldings thereof." (Paragraph [0001]). With respect to the reason why the carboxyl end groups of the aliphatic polyester resin are terminated, Matsumoto et al describe that "However, these aliphatic polyesters have a nature that the hydrolyzability in water at room temperature and a high temperature is very high, and they may be hydrolyzed even by water in air." (Paragraph [0003]). Thus, Matsumoto et al only teach that an aliphatic polyester is reacted with an oxazoline compound or oxazine compound to terminate the carboxyl end groups thereof. Matsumoto et al neither disclose nor suggest that a chain-lengthening reaction is conducted with the oxazoline compound.

With respect to the aliphatic polyester resin whose carboxyl end groups have been terminated, Matsumoto et al describe that "The aliphatic polyester resin according to the present invention can be formed or molded into fibers, films, sheets or various kinds of moldings from a state of a melt or solution, and is combined with a practically sufficient high molecular weight, heat resistance and resistance to hydrolysis, so that it can be utilized in a wider field than in the past." (Paragraph [0022]). However, the reason why the aliphatic polyester resin whose carboxyl end groups have been terminated has a practically sufficient

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high molecular weight is that a high-molecular weight aliphatic polyester resin is used as a starting material, and not that its molecular weight is highly increased by a chain-lengthening reaction of the aliphatic polyester resin with an oxazoline compound or oxazine compound. For example, with respect to polylactic acid used as a starting material, Matsumoto et al describe that "A weight average molecular weight in the case where polylactic acid is used in the present invention is preferably as high as possible, and is generally at least 50,000, preferably at least 80,000, more preferably 100,000 to 300,000, still more preferably 100,000 to 200,000. When the average molecular weight falls within the above range, strength properties of fibers, films and the like formed or molded from such a resin can be made excellent. Incidentally, it is generally difficult to increase the average molecular weight of polylactic acid to 400,000 or higher." (Paragraph [0010]) Matsumoto et al do not disclose the oxazoline as providing a chain length extending function.

In the Office Action, the Examiner asserted that use of the bis (2-oxazoline) inherently crosslinks, or chain extends, via reaction between two neighboring polylactic acid end groups and the claims require only a 10-35% increase in molecular weight. The Examiner concluded that the oxazoline will inherently bond two ends of neighboring polylactic acid chains and therefore that the small increase in molecular weight is inherent in the reaction of Matsumoto.

However, Applicants respectfully submit that the Examiner's interpretation of Matsumoto et al is in error and contrary to the actual teachings of Matsumoto et al. Matsumoto et al do not disclose that an aliphatic polyester resin such as polylactic acid is subjected to a chain-lengthening reaction with an oxazoline compound. In addition, it cannot

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be concluded that the reaction of the aliphatic polyester resin with the oxazoline compound inherently causes a chain-lengthening reaction, as the Examples of Matsumoto et al demonstrate otherwise. That is, the Examples of Matsumoto et al indicate that a solution specific viscosity ( $\eta_r$ ) is an index to a molecular weight and that the solution specific viscosity ( $\eta_r$ ) is obtained by measuring the viscosity of a solution with 3 g of a polymer sample dissolved in 100 ml of orthochlorophenol at 25° C by means of an Ostwald viscometer (Paragraph [0031]).

Specifically, Examples 1, 2 and 5 and Comparative Example 1 relate to poly(L-lactic acid) ("PLLA"). Example 1 of Matsumoto et al describes that heated and melted 2,2'-m-phenylenebis(2-oxazoline) ("PBO") was continuously added to PLLA chips in such a manner that a mixing ratio of PLLA to PBO is 99.59:0.41 (by weight), and these were fed into a twin-screw kneader extruder at a cylinder temperature of 220°C to react both components, thereby obtaining PLLA chips whose carboxyl end groups were terminated and which had a solution specific viscosity ( $\eta_r$ ) of 9.26. Example 2 of Matsumoto et al describes that PLLA and a styrene-2-isopropenyl-2-oxazoline copolymer ("EPC") were reacted in the same manner as in Example 1 except that a mixing ratio of PLLA to EPC was 90.00:10.00 (by weight), thereby obtaining PLLA chips whose carboxyl end groups were terminated and which had a solution specific viscosity ( $\eta_r$ ) of 8.23. Example 5 of Matsumoto et al describes that both components were reacted in the same manner as in Example 1 except that the mixing ratio of the PLLA to PBP was changed to 99.40:0.60 (by weight), thereby obtaining PLLA chips whose carboxyl end groups were terminated and which had a solution specific viscosity ( $\eta_r$ ) of 9.02.

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On the other hand, Comparative Example 1 of Matsumoto et al describes that PLLA chips whose carboxyl end groups were not terminated, and which had a solution specific viscosity ( $\eta_r$ ) of 9.12 were obtained in the same manner as in Example 1 except that the same PLLA as that used in Examples 1, 2 and 5 was fed into a twin-screw kneader extruder at a cylinder temperature of 220°C without adding the end terminating agent. Thus, a ratio of the solution specific viscosity ( $\eta_r$ ) of PLLA, whose carboxyl end groups were terminated, and which was obtained in each of Examples 1, 2 and 5, to the solution specific viscosity ( $\eta_r$ ) 9.12 of PLLA, whose carboxyl end groups were not terminated, and which is described in Comparative Example 1 of Matsumoto et al, is as follows:

Example 1:  $9.26/9.12 = 1.02$

Example 2:  $8.23/9.12 = 0.90$

Example 5:  $9.02/9.12 = 0.99$

As is apparent from these results, the solution specific viscosity ( $\eta_r$ ) of the poly (L-lactic acid) that is a starting material is not substantially improved according to the end terminating method of Matsumoto et al, and in fact is lowered in some cases, and therefore no significant chain-lengthening reaction occurs.

Example 3 and Comparative Example 3 of Matsumoto et al are directed to polyglycolic acid ("PGA"). Specifically, Example 3 of Matsumoto et al describes that heated and melted PBO was continuously added to PGA chips in such a manner that a mixing ratio of PGA to PBO is 99.04:0.96 (by weight), and these were fed into a twin-screw kneader



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extruder at a cylinder temperature of 270°C to react both components, thereby obtaining PGA chips whose carboxyl end groups were terminated, and which had a solution specific viscosity ( $\eta_r$ ) of 1.50. On the other hand, Comparative Example 3 of Matsumoto et al describes that PGA chips whose carboxyl end groups were not terminated and which had a solution specific viscosity ( $\eta_r$ ) of 1.41 were obtained in the same manner as in Example 3 except that the PGA was fed into a twin-screw kneader extruder at a cylinder temperature of 270°C without adding the end terminating agent.

Thus, a ratio of the solution specific viscosity ( $\eta_r$ ) of PGA whose carboxyl end groups were terminated as in Example 3, to the solution specific viscosity ( $\eta_r$ ) 1.41 of PGA whose carboxyl end groups were not terminated as in Comparative Example 3 of Matsumoto et al is as follows:

Example 3:  $1.50/1.41 = 1.06$

As is apparent from this result, the solution specific viscosity ( $\eta_r$ ) of the polyglycolic acid that is a starting material is not substantially improved according to the end terminating method of Matsumoto et al and therefore no significant chain-lengthening reaction occurs.

According to the end terminating method of Matsumoto et al, the aliphatic polyester resin and the end terminating agent are melt and kneaded at a high temperature, but are extruded by means of the twin-screw kneader extruder in a short kneading period of time. Therefore, the carboxyl end groups of the aliphatic polyester resin are terminated with the oxazoline compound, but no significant chain-lengthening reaction occurs. Matsumoto et al

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also neither teach nor suggest that high-molecular weight polyglycolic acid having a broad molecular weight distribution and excellent processability is obtained by a chain-lengthening reaction with the oxazoline compound as presently claimed.

Anticipation under 35 U.S.C. §102 requires that each and every element as set forth in the claims is found, either expressly or inherently described, in a single prior art reference, *In re Robertson*, 49 U.S.P.Q. 2d 1949, 1950 (Fed. Cir. 1999). In view of the failure of Matsumoto et al to expressly or inherently describe a high-molecular weight aliphatic polyester whose molecular weight has been highly increased by a chain-linked reaction with an oxazoline compound to the extent that a ratio  $Mw_2/Mw_1$  is at least 1.35, as recited in claims 1 and 11, Matsumoto et al do not anticipate claim 1 or claim 11, or any of the claims dependent thereon, under 35 U.S.C. §102. Accordingly, Applicants submit that the rejection under 35 U.S.C. §102(b) based on Matsumoto et al has been overcome, and reconsideration is respectfully requested.

Claims 1-4, 6-9, 11-13, 16 and 19-20 were rejected under 35 U.S.C. §102 (b) as being anticipated by Bonsignore (US 5,470,944). However, as set forth in detail below, Applicants submit that the high-molecular weight aliphatic polyesters and production process thereof defined by the present claims 1, 4, 7-9, 11, 16 and 20 are not anticipated by Bonsignore. Accordingly, this rejection is traversed and reconsideration is respectfully requested.

The high-molecular weight aliphatic polyester defined by independent claim 1 and the production process thereof defined by independent claim 11 have been discussed in detail. Bonsignore provides no teaching of such a polyester or production process. That is,

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Bonsignore discloses a degradable high molecular weight poly (lactic acid) comprising poly (lactic acid) polymeric units having terminal end groups selected from the group consisting of one of carboxyl and hydroxyl groups, and the polymeric units are coupled one to another by coupling agents selected from the group consisting of di-isocyanates, bis-epoxides, bis-oxazolines and bis-orthoesters (Abstract and claim 1).

However, Bonsignore fails to disclose important features of the invention. First, the aliphatic polyester according to the present invention is polyglycolic acid, containing, at most, 30% by weight of another cyclic monomer, whereas the polymer disclosed in Bonsignore is poly(lactic acid). Second, Bonsignore describes that bis-oxazolines are used as the coupling agents (Abstract and claim 1), but does not describe conditions under which the coupling is conducted with the bis-oxazolines. Therefore, Bonsignore does not indicate to one skilled in the art if any chain lengthening as claimed is achieved.

Third, the coupling processes specifically disclosed in Bonsignore include i) a process in which low molecular weight poly(lactic acid) having a hydroxyl group (OH) at both terminals thereof is coupled with a di-isocyanate; ii) a process in which low molecular weight poly(lactic acid) having a carboxyl group (COOH) at both terminals thereof is reacted with a di-isocyanate to form an unstable carbamic acid anhydride, after which carbon dioxide is then released by spontaneous decomposition to form a stable amide bond; iii) a process in which low molecular weight poly(lactic acid) is reacted with a di-isocyanate to synthesize an isocyanate capped prepolymer, and this prepolymer is reacted with the low molecular weight poly(lactic acid) to synthesize high molecular weight poly(lactic acid); iv) a process in which low molecular weight poly(lactic acid) is reacted with a di-isocyanate to synthesize an

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isocyanate capped prepolymer, and this prepolymer is reacted with polypropylene glycol, polyethylene glycol or bis-hydroxyethyl sulfone to synthesize high molecular weight poly(lactic acid); v) a process in which isocyanate-capped low molecular weight poly(lactic acid) is reacted with water to synthesize high molecular weight poly(lactic acid); vi) a process in which hydroxyl group (OH)-terminated low molecular weight poly(lactic acid) is reacted with a bis-epoxide to synthesize high molecular weight poly(lactic acid); vii) a process in which carboxyl group (COOH)-terminated low molecular weight poly(lactic acid) is reacted with a bis-epoxide to synthesize high molecular weight poly(lactic acid); and viii) a process in which low molecular weight poly(lactic acid) functionalized with a mercapto group at terminals is modified under mild oxidation conditions to synthesize high molecular weight poly(lactic acid) (columns 7-9). A process as presently claimed is not specifically disclosed.

Fourth, all the coupling processes disclosed in the Examples of Bonsignore are processes wherein a reaction is conducted over a long period of time under mild conditions. For example, Example 1 of Bonsignore describes that the carboxyl end groups of low molecular weight poly (lactic acid) ("PLA") having Mn of 2,500 were converted to hydroxyl groups, the hydroxyl terminated low molecular weight PLA was dissolved in acetone, and MDI (methylene bis-phenylisocyanate) was then added dropwise to the solution to conduct a reaction for 2 hours, thereby obtaining high molecular weight PLA. Example 2 of Bonsignore describes that hydroxyl terminated low molecular weight PLA and polypropylene glycol were dissolved in toluene, and MDI was added to the solution to conduct a reaction overnight in the presence of a tin catalyst (stannous octoate), thereby obtaining high molecular weight PLA. Example 3 of Bonsignore describes that HDI (hexamethylene di-

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isocyanate) was added to a toluene solution of low molecular weight PLA having Mn of 3,750 to conduct a reaction for 7 days at room temperature, thereby synthesizing NCO capped PLA prepolymer, and polypropylene glycol was then added to a solution of the NCO capped PLA prepolymer to conduct a reaction for 20 minutes at 100-200°C in the presence of a tin catalyst, thereby obtaining a tough rubbery mass. A process as presently claimed is not exemplified.

Fifth, Bonsignore only discloses the use of low molecular weight poly(lactic acid) having a molecular weight of about 2,000-15,000 as a starting material. Accordingly, Bonsignore not only fails to disclose the high increase in molecular weight by the coupling reaction of polyglycolic acid with an oxazoline as recited in claims 1 and 11, but also fails to teach or suggest the reaction conditions recited in claim 11 of the present application. On the other hand, as recited in claim 11 of the present application, in the process according to the present invention for producing high-molecular weight polyglycolic acid, polyglycolic acid having a weight average molecular weight of at least 30,000 is used as a starting material, and the polyglycolic acid and an oxazoline compound are subjected to a chain lengthening reaction at a high temperature of not lower than the melting temperature of the polyglycolic acid, but not higher than 300°C for 10 to 30 minutes. Finally, Bonsignore neither teaches nor suggests that high-molecular weight polyglycolic acid, whose molecular weight has been highly increased to the extent that a ratio of increase in molecular weight amounts to at least 1.35, and which has excellent heat resistance as demonstrated by a difference ( $T_2 - T_1$ ) of at least 5°C, can be obtained by such a chain-lengthening reaction.

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In view of these deficiencies in the teachings of Bonsignore, Bonsignore fails to describe, expressly or inherently, each and every element of the present claims. Thus, Bonsignore fails to anticipate the present claims under 35 U.S.C. §102, *In re Robertson, supra*. Accordingly, Applicants submit that the rejection under 35 U.S.C. §102(b) based on Bonsignore has been overcome. Reconsideration is respectfully requested.

Claim 15 was rejected under 35 U.S.C. 103 (a) as being unpatentable over Matsumoto or Bonsignore. Although this rejection is traversed, by the present amendment, claim 15 has been canceled, whereby this rejection is overcome. Reconsideration is respectfully requested.

Finally, claims 5, 10 and 17-18 were rejected under 35 U.S.C. 103 (a) as being unpatentable over Bonsignore in view of Matsumoto. This rejection is traversed and reconsideration is respectfully requested.

The distinctions between the presently claimed aliphatic polyesters and production processes thereof defined by claims 1 and 11 as compared with Matsumoto et al and Bonsignore are discussed above and apply equally as well to claims 5, 10, 17 and 18. Further, as described above, Matsumoto et al teach that a high molecular weight aliphatic polyester is reacted with an oxazoline compound or oxazine compound to terminate the carboxyl end groups thereof, and neither disclose nor suggest that the chain-lengthening reaction is conducted with the oxazoline compound to increase weight average molecular weight as required by claims 5 and 18. On the other hand, Bonsignore only discloses an increase in the molecular weight by the coupling reaction of the low molecular weight poly(lactic acid), and neither teaches nor suggests the high increase in the molecular weight

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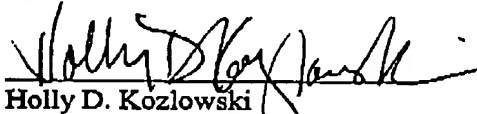
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of polyglycolic acid recited in claims 5 and 18 by the chain-lengthening reaction of polyglycolic acid.

Additionally, Applicants find no teaching or suggestion by Matsumoto et al or Bonsignore which would suggest to one of ordinary skill in the art to employ the oxazoline compound of claim 10 or the amount of oxazoline compound recited in claim 17 in a chain-lengthening reaction of polyglycolic acid. Accordingly, the combination of Matsumoto et al and Bonsignore fails to render obvious the high-molecular aliphatic polyester of claim 1, or claims 5 and 10 dependent thereon, and fails to render obvious the production process of claim 11, and claims 17 and 18 dependent thereon. Accordingly, the rejection under 35 U.S.C. §103 has been overcome. Reconsideration is respectfully required.

It is believed that the above represents a complete response to the Official Action, and places the present application in condition for allowance. Reconsideration and an early allowance are requested.

Respectfully submitted,



Holly D. Kozlowski  
Registration No. 30,468  
Dinsmore & Shohl LLP  
1900 Chemed Center  
255 East Fifth Street  
Cincinnati, Ohio 45202  
(513) 977-8568

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